

Notice of Allowability

Application No.

09/143,143

Examiner

JOHN D PAK

Applicant(s)

ASH, STEPHEN R.

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.


1. ☒ This communication is responsive to Applicant's reply of 6/1/2004.
2. ☒ The allowed claim(s) is/are 67-84 [renumbered as 1-18].
3. ☒ The drawings filed on 28 August 1998 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 8/20/03, 8/28/98
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Coy on 7/23/2004.

Cancel all claims and add the following new claims¹.

Claim 67 (New). An aqueous dialysate composition comprising:

water;

about 130 to about 150 mEq/L sodium;

about 0.4 to about 1.5 mEq/L magnesium;

about 2 to about 4 mEq/L calcium;

about 1 to about 4 mEq/L potassium;

about 90 to about 120 mEq/L chloride;

about 3 to about 5 mEq/L acetate;

about 30 to about 40 mEq/L bicarbonate;

glucose; and

an iron complex dissolved in the water, the complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of

¹ This amendment in effect (i) cancels claims 25-28, 33-37, 48-51, 56-59, 62 and 64, (ii) rewrites claims 24, 29, 32, 40-41, 46, 52-55 and 60, and (iii) and adds four dependent claims to specifically recite ferrous gluconate. Because the claims were renumbered in permanent red ink starting from the number 1 in the previous Office action, and given the fact that this case is now an IFW case, presentation of a new set of

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less than about 50,000, the iron complex having a concentration in the water to provide an iron concentration of from about 1 to about 250 µg/dl.

Claim 68 (New). The composition in accordance with claim 67, further comprising a member selected from the group consisting of dextrose, a sorbent and a surfactant dissolved or dispersed in the water.

Claim 69 (New). The composition in accordance with claim 67, wherein the aqueous dialysate composition is substantially hypertonic.

Claim 70 (New). The composition in accordance with claim 67, wherein the sodium, magnesium, calcium, potassium, chloride, acetate and bicarbonate are proportioned to prevent excessive ion removal from a patient's blood during dialysis of the blood with the composition.

Claim 71 (New). The composition in accordance with claim 67, wherein the iron complex is ferrous gluconate.

Claim 72 (New). A method for making an aqueous dialysate composition comprising, dissolving into water (i) about 130 to about 150 mEq/L sodium, about 0.4 to about 1.5 mEq/L magnesium, about 2 to about 4 mEq/L calcium, about 1 to about 4 mEq/L potassium, about 90 to about 120 mEq/L chloride, about 3 to about 5 mEq/L acetate, about 30 to about 40 mEq/L bicarbonate, and glucose, and (ii) an iron complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000 in an amount effective to provide an iron

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concentration in the water of from about 1 to about 250 µg/dl, to provide an aqueous dialysate composition.

Claim 73 (New). The method in accordance with claim 72, wherein the iron complex is ferrous gluconate.

Claim 74 (New). A method for making an aqueous dialysate composition, comprising:

providing a first aqueous solution comprising about 130 to about 150 mEq/L sodium, about 0.4 to about 1.5 mEq/L magnesium, about 2 to about 4 mEq/L calcium, about 1 to about 4 mEq/L potassium, about 90 to about 120 mEq/L chloride, about 3 to about 5 mEq/L acetate, about 30 to about 40 mEq/L bicarbonate, and glucose; and

introducing into the first aqueous solution an iron complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000, to provide a second aqueous solution useful as an aqueous dialysate composition, the second aqueous solution having an iron concentration of from about 1 to about 250 µg/dl.

Claim 75 (New). The method in accordance with claim 74, wherein the complex is introduced in a predetermined amount, the amount being selected based upon the iron needs of a given patient.

Claim 76 (New). The method in accordance with claim 74, wherein the iron complex is ferrous gluconate.

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Claim 77 (New). An aqueous dialysate concentrate composition, comprising:
water;
a plurality of electrolytes and glucose dissolved in the water; and
an iron complex dissolved in the water, the complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000;

wherein the electrolytes, glucose and iron complex have concentrations in the water whereby the composition is effective for dilution to provide a dialysate composition having about 130 to about 150 mEq/L sodium, about 0.4 to about 1.5 mEq/L magnesium, about 2 to about 4 mEq/L calcium, about 1 to about 4 mEq/L potassium, about 90 to about 120 mEq/L chloride, about 3 to about 5 mEq/L acetate, about 30 to about 40 mEq/L bicarbonate, glucose, and an iron concentration of from about 1 to about 250 µg/dl.

Claim 78 (New). The aqueous dialysate concentrate composition in accordance with claim 77, further comprising a member selected from the group consisting of dextrose, a sorbent and a surfactant dissolved or dispersed in the water.

Claim 79 (New). The aqueous dialysate concentrate composition in accordance with claim 77, wherein the electrolytes have a concentration in the water of from about 7692 mEq/L to about 12,980 mEq/L.

Claim 80 (New). The aqueous dialysate concentrate composition in accordance with claim 77, wherein the iron complex is ferrous gluconate.

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Claim 81 (New). A method for making an aqueous dialysate concentrate composition comprising, dissolving into water (i) a plurality of electrolytes and glucose, and (ii) an iron complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000, to provide an aqueous dialysate concentrate composition;

wherein the electrolytes, glucose and iron complex have concentrations in the water whereby the composition is effective for dilution to provide a dialysate composition having about 130 to about 150 mEq/L sodium, about 0.4 to about 1.5 mEq/L magnesium, about 2 to about 4 mEq/L calcium, about 1 to about 4 mEq/L potassium, about 90 to about 120 mEq/L chloride, about 3 to about 5 mEq/L acetate, about 30 to about 40 mEq/L bicarbonate, glucose, and an iron concentration of from about 1 to about 250 µg/dl.

Claim 82 (New). The method in accordance with claim 81, wherein the electrolytes in said concentrate composition have a concentration in the water of from about 7692 mEq/L to about 12,980 mEq/L and wherein the iron complex in said concentrate composition has a concentration in the water effective to provide an iron concentration in the water of from about 0.03 to about 10 mg/dl.

Claim 83 (New). The method in accordance with claim 81, further comprising introducing into the water a member selected from the group consisting of dextrose, a sorbent and a surfactant.

Claim 84 (New). The method in accordance with claim 81, wherein the iron complex is ferrous gluconate.

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The following is a summary of the status and numbering of the claims after entry of this Examiner's Amendment.

<u>Original Claim</u>	<u>Corresponding New Claim</u>	<u>Renumbering at allowance</u>
24	67	1
29	68	2
65	69	3
66	70	4
N/A	71	5
32	72	6
N/A	73	7
40	74	8
41	75	9
N/A	76	10
46	77	11
52	78	12
53	79	13
N/A	80	14
54	81	15
55	82	16
60	83	17
N/A	84	18

The following is an Examiner's statement of Reasons for Allowance:

First, the closest prior art is Gupta (US 6,689,275, 12/31/1996 filing date).

Because the provisional application to which the instant application relies on for domestic priority does not provide adequate descriptive support for any of the claims, as presently amended, the effective filing date of the claims (6/5/1997) does not predate Gupta's filing date, and hence Gupta is applicable as prior art.

Second, having established that Gupta is available as prior art with respect to the instant claimed invention, it has been determined that the instant claimed invention is

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patentable over Gupta and the prior art as a whole. While Gupta discloses adding a noncolloidal ferric compound such as ferric pyrophosphate to a dialysis solution, the specific mixture of ingredients that is claimed in the instant application is not disclosed or fairly suggested. Gupta discloses that "dialysis concentrates are usually supplied by the manufactures either as a solution ready to use or as premixed powder that is added to purifies water in large reservoirs" (column 5, lines 15-18). Gupta's disclosed ingredients and their range of concentrations (column 5, lines 26-29) fail to specify all of the dialysate ingredients and their concentrations, *in combination with iron in a dialysate composition*, as claimed in the instant application. In the Ash declaration filed by applicant on 5/20/2002, applicant provides evidence that formulating iron into a dialysate composition would have raised considerable toxicity concerns to the ordinary skilled artisan at the time the invention was made (see for example, paragraphs 5 and 7). Given the totality of the fact situation at the time the invention was made, one having ordinary skill in the art, without having the disclosure of the instant application as guidance, would have not have been sufficiently motivated to specifically utilize a mixture of dialysate ingredients that comprises the instant invention: about 130 to about 150 mEq/L sodium, about 0.4 to about 1.5 mEq/L magnesium, about 2 to about 4 mEq/L calcium, about 1 to about 4 mEq/L potassium, about 90 to about 120 mEq/L chloride, about 3 to about 5 mEq/L acetate, about 30 to about 40 mEq/L bicarbonate, glucose, and an iron complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000 in an amount effective to provide an iron concentration in water of from about 1 to about 250 µg/dl.

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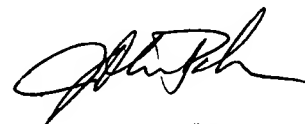
Therefore, the claimed invention as a whole is deemed to be patentable over the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machines is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner John Pak whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is **(571) 272-1600**.



**JOHN PAK
PRIMARY EXAMINER
GROUP 1600**